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### **CONDITIONAL PETITION FOR EXTENSION OF TIME**

If any extension of time for this response is required, Applicants request that this be considered a petition therefore. Please charge the required fee to Deposit Account No. 14-1263.

### **ADDITIONAL FEES**

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### **REMARKS**

Claims 8, 10-12 and 14-23 have been canceled and new claims 24-34 have been added in the application.

The claims 8, 10-12 and 14-23 had been held unpatentable over Sanchez.

Applicants' new claims are believed to place the claims in condition for allowance.

### **The Entire Application Should be Examined – Restriction Would be Improper**

Applicants respectfully suggest that the prior art search performed to date is likely to have provided a sufficient body of references to prosecute the new claims. Accordingly, it is suggested that the Examiner can examine the complete application without serious burden.

The MPEP states, "[t]here are two criteria for a proper requirement for restriction between patentably distinct inventions:

- (1) The inventions must be independent ...or distinct as claimed ...;  
*and*
- (2) *There must be a serious burden on the examiner if restriction is not required .... [All emphasis added.]*

Further, the MPEP clearly provides that “[i]f the search and examination of an entire application can be made without serious burden, the examiner *must* examine it on the merits, *even though it includes claims to distinct or independent inventions*. Consequently, the Examiner’s authority to insist upon restriction *only* extends to those situations where the failure to insist upon restriction would subject the Examiner to serious burden. MPEP § 803 – “Restriction — When Proper.”

In accordance with PTO procedure, Applicants respectfully solicit examination of the entire application.

**The New Claims are Supported by the Specification and  
do not Introduce New Matter.**

The new claims provide, in part, for a method of affecting existing levels of sebum production. Such a method is not disclosed in Sanchez, as that reference only teaches and suggests compositions for delipidating the skin using oil-free cyclodextrin containing compositions. See e.g., Abstract; Field of Invention; Summary of Invention.

Sanchez does not provide a single suggestion that reasonably permits persons with skill to interpret Sanchez’s compositions as providing a preventative measure against sebum production. Sanchez provides no teaching or suggestion that his discloses compositions can alter the synthetic and secretory activity of the affected sebaceous glands.

*mechanism*

In contrast, Applicants’ methods are disclosed for the “prophylaxis and treatment of mild forms of acne and for the prophylaxis and treatment of seborrhea.”

Specification, page 1, lines 14-15; page 4, line 24 to page 5, line 32; and original claims.

As asserted in the specification “*the prior art did not give the slightest indication of the use according to the invention as an antiseborrheic active principle.*” See page 6, lines 6-7. This conclusion is equally correct when evaluating the entirety of Sanchez’s disclosure.

Therefore, new claims 24-29 are patentably distinct on their face over Sanchez. Accordingly, Applicants respectfully request that the previous rejection under § 103(a) be withdrawn with respect to these claims.

Claims 30-35 are drawn to a skin-cleansing method that employs compositions having an oily-phase. The use of such a method is clearly disclosed in several areas of the specification, e.g., pages 13-15.

As discussed in detail below, Sanchez’s disclosure relates to essentially oil-free compositions. The Examiner has cited text from Sanchez suggesting the use of delipidating creams or lotions or gels. However, Examiner completely ignores Sanchez’s comments qualifying such use. For example:

[i] that creams or lotions or gels be used only in cleansing cerumen from the ear canal, and

[ii] that in formulating the cream or lotion or gel that “it is crucial” that the formulations do not contain compounds that would complex with the cyclodextrins’ hydrophobic core, and thus compete with cerumen’s “various lipid-like substances which include fatty acids and waxes.” In other words, there should be no oily or waxy substances in contact with the cyclodextrin prior to applying to the skin. This is in direct contradistinction with the composition used in the method of claims 30-34.

In view of the totality of Sanchez's teachings, it is clear that Sanchez is teaching away from the subject matter in claims 30-34. On this basis alone, the rejection under § 103(a) should be withdrawn.

**The Claims are Patentably Distinct From Sanchez's  
Oil-Free Delipidating Compositions**

MPEP 2141.02 makes it quite clear that "[a] prior art reference must be considered in its entirety, i.e. as a whole, including portions that would lead away from the claimed invention." (see MPEP 2141.02; W.L. Gore & Associates, Inc. v. Garlock, Inc., 220 USPQ 303 (Fed. Cir. 1983)) (Emphasis added).

Applicants respectfully suggest that Examiner has not considered the Sanchez reference's express teachings and suggestions that would lead persons of ordinary skill away from the method based on an oily, cyclodextrin formulation as described in claims 30-34.

Sanchez expressly teaches in several instances, that his compositions should be *oil and lipid-free*. For example:

- "The present invention provides delipidating compositions containing essentially oil-free "empty" cyclodextrins compositions"; e.g., page 2, lines 8-10.
- "Compositions for use in delipidation should be essentially free of oil." See page 2, lines 25-26.
- "The compositions of the invention are basically dry solids or aqueous solutions...." See page 2, lines 26-28.
- Sanchez's disclosed modes of applying the cyclodextrins are consistent with the teaching of oil-free compositions – dry or pre-moistened sponges, gauze, paper fabric, roll-ons, aerosols; "immersion in or sprinkling by water

containing the cyclodextrin”; “[s]uitable carriers may be in the form of powder, oil-free gels or suspensions.” See page 3, lines 4-24.

- “Aqueous compositions are a preferred class of compositions. However, the compositions may contain alcohols or other carriers that are not firmly complexed to the cyclodextrin.” See page 3, lines 28-30. NOTE – the “firmly complexed” carriers referred to are lipophilic molecules that interact with cyclodextrins’ hydrophobic core. See Sanchez, page 2, lines 19-20, and 25-28. Thus, Sanchez’s cyclodextrin carriers are *non-lipophilic*.
- Sanchez’s exemplified embodiments *only disclose aqueous solutions* or suspension. See Examples 1-6.

New claims 30-34 now require that the composition be in a form containing at least one lipophilic or oily component. As such, the claimed method cannot even remotely be considered as suggested or taught by Sanchez’s aqueous or essentially oil-free compositions.

Accordingly, the claims are patentably distinct over Sanchez and the rejection under § 103(a) should be withdrawn.

#### Sanchez Does not Disclose the use of Oily Creams, Lotions or Gels.

Examiner’s assertion that “Sanchez also teaches that the composition can be incorporated into gels, lotions, and creams....” is taken completely out of context and further ignores the entirety of Sanchez’s teachings. By ignoring the totality of Sanchez’s teachings, Examiner simply picks out claim limitations from Sanchez in order to improperly reconstruct the claims by hindsight. This is indisputably contrary to PTO guidelines of proper analysis under § 103(a). MPEP § 2141 – *Basic Considerations Which Apply to Obviousness Rejections.*

Sanchez only discloses gels, lotions and creams for use in reducing cerumen in the ear canal. Page 3, line 36-37. This was not a general suggestion that his invention should be used for cleansing the skin of sebum.

Further, Sanchez immediately qualifies in the next sentence, by stating that the composition must not have any complexed molecules that are “easily displaced by components of cerumen, which is a mixture of debris, hair, dirt and various lipid-like substances which include fatty acids and waxes.” Bottom page 3 to top page 4.

Thus, Sanchez discloses that even if creams and lotions are used, they must not have certain components, without providing a single example of what those components are. Persons with ordinary skill could not reasonably use this suggestion to arrive at the claimed composition or any other composition for that matter.

There is not a single teaching, suggestion or exemplified embodiment in Sanchez indicating that even in the special case of removing cerumen from the ear canal, that he departs from his core invention – an oil-free, dry or aqueous composition having cyclodextrins.

For this reason, Examiner’s citation of portions of Flick and Remington is also wholly improper. There is no teaching or suggestion in Sanchez to suggest that it be combined with components cited on these pages – e.g., castor oil and caprylic acid. This is an attempt by Examiner to reconstruct the claims by hindsight.

It has long been held that “[i]t is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.” (see In re Wesslau, 147 USPQ 391, 393 (CCPA 1965)).

Examiner’s cited text on page of Sanchez is not legally sufficient as a disclosure of *oil-free* gels or creams and lotions under § 103(a), but merely an

invitation to develop such a composition. There are no examples and no specific teachings of how to accomplish this.

"The question under 35 U.S.C. § 103 is not whether the differences [between the claimed invention and the prior art] would have been obvious" but "whether the claimed invention *as a whole* would have been obvious." (emphasis in original). In Stratoflex, Inc. v. Aeroquip Corp., 218 USPQ 871, 877 (Fed. Cir. 1983).

Applicants respectfully suggest that according to such an analysis, new claims 24-34 are patentably distinct over Sanchez.

#### CONCLUSION

Applicants respectfully submit that in view of the amendments and the foregoing remarks, the present claims are in condition for allowance, and that allowance be granted.

Respectfully submitted,  
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